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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/821,930  | 04/12/2004  | Dario Neri           | ELLIS-0002-P02-C01      | 3681             |
| 23599   | 7590        | 10/23/2006           | EXAMINER                |                  |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      | PORTNER, VIRGINIA ALLEN |                  |
|   |             | ART UNIT             | PAPER NUMBER            |                  |
|   |             |                      | 1645                    |                  |

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                  |                         |  |
|------------------------------|----------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>           | <b>Applicant(s)</b>     |  |
|                              | 10/821,930                       | NERI ET AL.             |  |
|                              | <b>Examiner</b><br>Ginny Portner | <b>Art Unit</b><br>1645 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 April 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-34 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 4/12/04 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/05/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application      |
|  | 6) <input checked="" type="checkbox"/> Other: <u>sequence letter</u> . |

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## **DETAILED ACTION**

Claims 1-34 are pending.

### ***Sequence Letter***

1. This application contains Sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

2. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.136. In no case may an applicant extend the period of response beyond the six month statutory period and the response period is the time set in this action. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Sequences which need assignment of a SEQ ID NO were found at:

1. page 3, lines 16-18;
- 1 page 19, lines 23, 26-28, 30-31;
- 2 page 23, lines 2-4, 6-8, 11-13 and 31;
- 3 page 24, lines 1, 3-4 and 7;
- 4 page 34, Table 1, page 34,
6. Claims 7 and 10 and; Figures 1 and 6.

### ***Drawings***

- The Brief Description of the Drawing should be amended to recite SEQ ID Nos that identify the amino acid sequences and nucleic acid sequences shown in Figures 1B and 6.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13 and 18 are, drawn to antibodies which specifically bind to a fibronectin and a kit comprising said antibodies, classified in class 530 , subclass 387.1 .
- II. Claims 14-17,drawn to a methods of detecting fibronectin ED-B domain, either in vivo or in vitro associated with tumors, diabetes, macular degradation , classified in class 435, subclass 7.1.
- III. Claim 19, 25-27 (in vivo applications only), drawn to in vivo therapy associated with treating a host with an antibody, classified in class 424, subclass 158.1.
- IV. Claims 20-34 are, drawn to antibodies conjugates and methods of using the conjugate antibodies for treatment of angiogenesis, classified in class 424, subclass 178.1.
- V. Claim 35 is, drawn to a trimethylstannylbenzoic acid classified in class 424, subclass 1.73 .

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case product as claimed can be used in a materially different process of using that product, wherein the antibodies of Group I may be used for in vivo or in vitro

detection of fibronectin as well as in the immunotherapy of a host with antibodies which specifically provide a therapeutic effect in vivo, as well as in method of purifying antigen to which the antibodies specifically bind.

4. Inventions Group I and Group IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as antibodies for incorporation into diagnostics, in methods of purifying a protein and in the production of molecular image polymers the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibodies of Group I and the organic stannylbenzoic acid do not share any structural, functional or biological effects in common and therefore define independent and distinct inventions.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

### **Ochiai/Brouwer Rejoinder**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***General Observations***

#### ***Oath/Declaration***

1. This instant Application claims priority to two US Applications now pending in the United States Patent Office, and states that the Application claims foreign priority under 35 U.S.C. 119. The priority claimed is not foreign priority.

#### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01

3. The disclosure is objected to because of the following informalities: At page 15, lines 5 and 7, hyperlinks to sites on the Internet are recited. This is not permitted in a US Application. Appropriate correction is required.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Mark Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp  
October 13, 2006

  
MARK NAVARRO  
PRIMARY EXAMINER